Office - Supreme Court, U.S.
FILED
FEB 11 1982
ALEXANDER L. STEVAS,
CLERK

No. 80-2182
No. 81-11

IN THE SUPREME COURT OF THE UNITED STATES
October Term, 1981

INWOOD LABORATORIES, INC., and PREMO PHARMACEUTICAL LABORATORIES, INC.,
Petitioners,

vs.

IVES LABORATORIES, INC.,
Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

REPLY BRIEF OF PETITIONER INWOOD LABORATORIES, INC.

MILTON A. BASS
BASS, ULLMAN & LUSTIGMAN
Attorneys for Petitioner Inwood Laboratories, Inc.
747 Third Avenue
New York, N.Y. 10017
(212) 751-9494

OF COUNSEL:

JACOB LAUFER
STEVEN R. TROST
LAWRENCE H. ROTH

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

ARGUMENT 1

I. This Court Should Definitively Resolve The Controversy Between The Parties 1

II. There Has Been No Showing Of Trademark Infringement Under The Second Circuit's Theory Of Liability 8

III. The Brand-Name Companies' Absolute Denial of Functionality For Pharmaceutical Colors Cannot Be Sustained .. 14

IV. Ives' Standard For Contributory Liability Should Be Rejected as Contrary To The Public Interest 37

CONCLUSION 45

Contents

Page

TABLE OF AUTHORITIES

CASES CITED

A.H. Robins Co. v. Medicine Chest Corp., 206 U.S.P.Q. 1015 (E.D.Mo. 1980) 42

American Footwear Corp. v. General Footwear Co. Ltd., 609 F.2d 655 (2d Cir. 1979), cert. denied, 445 U.S. 951 (1980) 10

Artus Corp. v. Nordic Co. Inc., 512 F.Supp. 1184 (W.D.Pa. 1981) 28

Biocraft Laboratories, Inc. v. Merck & Co., Inc., ____ F.Supp. ____, Civ. Action No. 77-693 (D.N.J. Oct. 2, 1980) 27-28

Boehringer Ingelheim G.m.b.H. v. Pharmadyne Laboratories, 211 U.S.P.Q. 1163 (D.N.J. 1981) 10,11

Contents

Page

Certified Color Mfg. Ass'n v. Mathews, 543 F.2d 284 (D.C.Cir. 1976) 34-35

Coca-Cola Co. v. Snow Crest Beverages, 64 F.Supp. 980 (D.Mass. 1946), aff'd, 162 F.2d 280 (1st Cir.), cert. denied, 332 U.S. 809 (1947) 37

Compco Corp. v. Day-Brite Lighting, Inc., 376 U.S. 234 (1964) 4

Famolare, Inc. v. Melville Corp., 472 F.Supp. 738 (D.Haw. 1979), aff'd without opinion, 652 F.2d 62 (9th Cir. 1981) 41

Farm Service Inc. v. United States Steel Corp., 90 Ida. 570, 414 P.2d 898 (1966) 8

Fisher Stores Inc. v. All-Nighter Stove Works Inc., 626 F.2d 193 (1st Cir. 1980) 10

Kalem Co. v. Harper Bros., 222 U.S. 55 (1911) 44-45

Pharmaceutical Mfrs. Ass'n v. Whelan, ____ N.Y.2d ____, No. 650 (Dec. 22, 1981) 36

Contents

Page

Pharmaceutical Society of State of New York v. Lefkowitz, 586 F.2d 953 (2d Cir. 1978) 11

Plastilite Corp. v. Arlite Plastics Co., 390 F.Supp. 1141 (D.Neb. 1975), rev'd on other grounds, 526 F.2d 1078 (8th Cir. 1975), cert. denied, 425 U.S. 938 (1976) 33

Prestonettes, Inc. v. Coty, 264 U.S. 359 (1924) 13

Public Citizen v. Foreman, 631 F.2d 969 (D.C.Cir. 1980) .. 34

Schmidt Mfg. Co. v. Sherrill Industries Inc., 249 F.Supp. 480 (W.D.N.C. 1965) 33

Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225 (1964) 4

SK&F Co. v. Premo Pharmaceutical Laboratories Inc., 625 F.2d 1055 (3d Cir. 1980) 28

Telemed Corp. v. Tel-Med Inc., 588 F.2d 213 (7th Cir. 1978) 10

Contents

Page

Universal City Studios, Inc. v. Ideal Publishing Corp., 195 U.S.P.Q. 761 (S.D.N.Y. 1977) 8

Vitarroz Corp. v. River Brand Rice Mills Inc., 266 F.Supp. 981 (S.D.N.Y. 1967) 33

Winthrop Chemical Co. v. Blackman, 246 App.Div. 234, 285 N.Y.S. 443 (1st Dep't 1936) 13

Zenith Laboratories, Inc. v. Eli Lilly & Co., 460 F.Supp. 812 (D.N.J. 1978) 5

OTHER AUTHORITIES CITED

Biron and Caringman, "Chromo Confusion: A New Type of Pill - Pill 'Interaction' in Cardiology," 110 CMA J. 1346-48 (1974) 25

Blackwell, "Treatment Adherence, 129 BRIT.J.PSYCH. 513 (1976) 24

Blumenthal, Burke & Shapiro, "The Validity of Identical Matching Placebos," 31 ARCH.GEN.PSYCH. 214 (Aug. 1974) 25

Contents

Page

"Capsule Color Considerations" (Parke-Davis, Division of Warner-Lambert Co. 1980) .. 22-24,36

Chambers, "Colour - The Drug Companies Seek Protection", [1976] NEW ZEALAND L.J. 472 4

"Competition in the Drug Industry," Hearings Before the Subcomm. on Oversight & Investigations of the Comm. on Energy and Commerce, No. 97-35, 97 Cong., 1st Sess. (March 10, 1981) 6

96 CONG.REC. S53-54 (daily ed. Jan. 4, 1950) (Remarks of Sen. Fulbright) 35

Cornish, "Same Again - Same Substance of Same Maker?", [1972] BRIT.BUS. LAW J. 4

Dickinson, "Washington Report," Pharmaceutical Technology (Oct. 1981) 22

"Drug Product Selection," Staff Report to the Federal Trade Commission (Bureau of Consumer Protection, Jan. 1979) 19

FDA CONSUMER (Oct. 1980) 32

FDA ENFORECEMENT REPORTS (1981) .. 18

Contents

Page

FDA Office of Planning & Evaluations, "An Analysis of Prescription Recall Rates" (Apr. 1980) 17-18

Hackl, "Color: A Language of Persuation," ART PRODUCT NEWS, Vol.3, No.6 (1981) 34

Hackl, "Hidden Meaning of Color," GRAPHIC ARTS BUYER, Vol.12, No.5 (1981) 34

"HEW News," P-78-34 (Sept. 13, 1978) 18

Jacobs & Nordan, "Classification of Placebo Drugs: Effect of Color," 49 PERCEPTUAL & MOTOR SKILLS 367-372 (1979) 25

Karl, "First Amendment Considerations," Practising Law Institute Handbook #141, GENERIC TRADEMARKS, 53-68 (Dec. 1981) 8

Lasagna, "Placebos," 193 SCIENTIFIC AMERICAN 68-71 (1955) 31

Luscher, THE LUSCHER COLOR TEST (Pocket Books, N.Y., 1971) 34

Contents

Page

Mazzullu & Lasagna, "Take Thou . . . But Is Your Patient Really Taking What You Prescribed?", DRUG THERAPY at 11-15 (Nov. 1972) 30-31

McCarthy, TRADEMARKS AND UNFAIR COMPETITION, $25.2 (1973) 41

Most, "Color Scheming," AMERICAN WAY 28 (May 1981) ... 34

Nimmer, 3 NIMMER ON COPYRIGHT, $12.04 (1980) 41

"Prescription Drug Labelling and Price Advertising," Hearings Before the Subcomm. on Consumer Protection & Finance for H.Comm. on Interstate & Foreign Commerce, No. 94-153 (94th Cong., 2d Sess. 1976) ... 29-30

"The Scientific Evaluation of Drug Equivalency", Proceedings of a Colloquim - Washington, D.C., June 14, 1974 EXCERPTA MEDICA (Wash., D.C., 1974) 20-21

Schwartz, "The Elderly Patient and His Medications," GERIATRICS 517 (1976) 25

Contents

Page

S.Rep. #795, COLOR ADDITIVE AMENDMENTS OF 1959, Report to accompany S.2197, 86th Cong., 1st Sess. (1959) 33

STATUTES CITED

17 U.S.C. §271(b) 43

§33(b)(4) of the Lanham Act, 15 U.S.C. 1115(b)(4) 13

N.Y. Education Law, §6810(6)(b) (McKinney's Supp. 1981) 11

N.Y. Education Law §6826 (McKinney's Supp. 1981) 12

MISCELLANEOUS

46 F.R. 32,880 (June 25, 1981) ... 33

46 F.R. 47,623 (Sept. 29, 1981) .. 25

47 F.R. 444 (Jan. 5, 1982) 25

No. 80-2182
No. 81-11

IN THE SUPREME COURT OF THE UNITED STATES
October Term, 1981

INWOOD LABORATORIES, INC., et al.,
Petitioners,

vs.

IVES LABORATORIES, INC.,
Respondent.

REPLY BRIEF OF PETITIONER INWOOD LABORATORIES, INC.

I. THIS COURT SHOULD DEFINITIVELY RESOLVE THE CONTROVERSY BETWEEN THE PARTIES

Contrary to the contention of Ives Laboratories, Inc. ("Ives") and its amici, brand-name drug companies have the burden to justify their request for a monopoly of color not subject to patent, copyright or trademark protection. The lower court held that petitioners' advertising catalogs "suggested by implication" that pharmacists engage in unlawful conduct. Petitioners, including Inwood Laboratories, Inc.

("Inwood"), were therefore held liable as "contributory infringers." Relying heavily on the reasoning of a series of cases decided in the United States District Court for the District of New Jersey,[1] Ives abandons the Second Circuit's analysis[2] and argues that mere similarity of capsule color is enough to establish contributory liability since petitioners could have anticipated that such similarity would make it easier for some pharmacists to engage in unscrupulous conduct. This Court is thus asked to affirm the finding below on the alternative

---

[1]See cases cited in Inwood's Main Brief at 42, n.77.

[2]Paradoxically, the amicus brief of the Pharmaceutical Manufacturers Association ("PMA") in effect concedes the error of the Second Circuit's opinion. PMA therefore asks this Court to dismiss the writ of certiorari. This argument is patently frivolous. That the Second Circuit by all accounts decided the case improvidently requires that its decision be reversed, and not that the writ be classified as having been improvidently granted.

rationale and even the supposed record of the cases decided in New Jersey.[3]

Although urging affirmance on an alternative ground to find liability under §32 of the Lanham Act [15 U.S.C. §1114], Ives argues that this Court avoid any review of the §43(a) [15 U.S.C. §1125(a)] issues presented in this case.[4] It would not serve the interests of justice to leave for another day issues which are necessary for a definitive resolution of the pharmaceutical color/trademark controversy. Judicial economy requires that one rule be established for determining the theory of contributory liability, whether under §32 or §43(a). In the absence of contributory liability under

---

[3]See PMA Brief at 14-15, 23-26.

[4]Ives' avoidance of §43(a) is inconsistent with its reliance on the New Jersey cases which, as it admits, are based inter alia upon a violation of §43(a). See Ives Brief at 25.

federal law, the "Sears/Compco"[5] principles dictate that any state law unfair competition theory which Ives may have must fail. This Court is also in as good a position as the District Court and the Court of Appeals to review the documentary evidence which fails to show any secondary meaning for the colors blue and blue/red.[6] Even assuming secondary meaning of some sort, its only relevance as expressly found in the New

---

[5]Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225 (1964); Compco Corp. v. Day-Brite Lighting, Inc., 376 U.S. 234 (1964).

[6] "It ought not to be presumed that because, thanks to a patent, all the supplies of a drug have for a considerable period come from the patentee, therefore the public want[s] the drug made by him, rather than just the drug." W.R.Cornish, "Same Again--Same Substance of Same Maker?" [1972] BRIT. BUSINESS LAW J. 141, 142.

See also R. Chambers, "Colours--The Drug Companies Seek Protection" [1976] NEW ZEALAND L.J. 472, 476 (Nov. 2, 1976) (noting that "colour is an important means of identification of the drug, rather than of the drug's source of manufacture.") [emphasis in original]; Inwood's Main Brief at n.49 and accompanying text.

Jersey cases is the extent that it contributes to a manufacturer's liability for the acts of pharmacists who unlawfully dispense its product. The issues which must necessarily be decided by this Court, in light of the alternative theory of contributory liability advanced by Ives, thus encompass all of the elements needed for resolution of the overall controversy.

Finally, it is of the greatest importance that this Court definitively determine these issues. Presently, the historical practice of utilizing similar colors[7] has been subjected to successful challenge in a barrage of litigation against the generic drug companies. Petitioners ask this Court to hold that copying of capsule or tablet

---

[7]Neither Ives nor its amici make any effort to challenge the uncontradicted testimony that this has been the general practice for more than 40 years. See also Zenith Laboratories, Inc. v. Eli Lilly & Co., 460 F.Supp. 812, 819 (D.N.J. 1978).

color is permissible as a lawful aspect of competition in the prescription drug industry.[8] Generic companies must be in a position to know at the very outset whether their decision to utilize particular colors will be lawful.[9] They cannot afford to take the risk that their decision will be challenged on a case-by-case basis as each brand-name company separately seeks to establish that its colors are entitled to protection. Knowing that the smaller generic companies are unable to bear the financial burden inherent in multiple

---

[8]Color performs various functional purposes in the distribution and use of prescription drugs. For fully effective competition, such use should not constitute liability under §32 or §43(a) of the Lanham Act.

[9]This Court's decision will have vast and imminent ramifications for the drug industry. Ten prescription drugs, including Valium, which are due to come off patent in the next four years involve annual sales of over $1 billion. See "Competition in the Drug Industry," Hearings before the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce, No. 97-35 (97th Cong. 1st Sess., Mar. 10, 1981) at 13.

litigation of this kind, brand-name companies have already obtained a series of consent judgments against continued utilization of similar drug colors.[10] Inwood therefore respectfully requests that this Court reverse the Ives IV decision and definitively reject the arguments advanced by Ives and its amici which seek to obtain a color monopoly for unfair competitive purposes.

---

[10]See, e.g., Ives Laboratories, Inc. v. Bioline Laboratories, Inc., Civ. Action No. 81-914 (D.N.J. Consent Judgment entered against defendant Henry Schein, Inc. Oct. 15, 1981); American Cyanamid Co. v. Par Pharmaceutical, Inc., Civ. Action No. 81-1001 (D.N.J. Consent Judgment entered June 17, 1981); Bristol-Myers Co. v. Par Pharmaceutical, Inc., Civ. Action No. 81-290 (D.N.J. Consent Judgment entered Apr. 14, 1981); Boehringer Ingelheim, G.m.b.H. v. Chelsea Laboratories, Inc., Civ. Action No. 80-3759 (D.N.J., Consent Judgment entered Feb. 10, 1981); Schering Corp. v. Zenith Laboratories, Inc., Civ. Action No. 80-2546 (D.N.J. Consent Judgment entered Sept. 19, 1980).

II. THERE HAS BEEN NO SHOWING OF TRADEMARK INFRINGEMENT UNDER THE SECOND CIRCUIT'S THEORY OF LIABILITY

The most obvious reason for Ives' abandonment of the Second Circuit's reasoning concerning contributory trademark infringement[11] is that its finding was premised on the theory that trademark infringement was shown by the "additional evidence" of so-called "mislabeling." As shown in Inwood's main brief (without any contradiction by Ives and its amici) all pharmacists, pursuant to a prescription which authorized

---

[11] It also enables Ives to avoid the critical question of whether the Second Circuit impermissibly restricted petitioners' First Amendment rights. In addition to the cases cited at pp. 39-41 of Inwood's Main Brief, see also Farm Service, Inc. v. United States Steel Corp., 90 Ida. 570, 414 P.2d 898 (1966); Universal City Studios, Inc. v. Ideal Publishing Corp., 195 U.S.P.Q. 761, 762 (S.D.N.Y. 1977). See generally D. Karl, "First Amendment Considerations" appearing in Practising Law Institute Handbook #141, Generic Trademarks 53-68 (December 1981). Ives now claims it never intended to restrict the exercise of petitioner's free speech rights. But see Ives' Complaint at Count III [J.A. 22-23].

generic substitution, dispensed the appropriate generic product when available. A few placed the word "Cyslospasmol" on the container accompanied by written and/or oral notice that the product was "generic Cyclospasmol." This additional evidence was supposedly critical to the finding of contributory trademark infringement since the earlier evidence relating to "illegal substitution" had expressly been found in Ives II to be insufficient to establish contributory liability. Ives II at Pet.App. 36a, 52a-53a.

Ives makes no direct response to the threshold issue that there must be a showing of primary trademark infringement before finding liability for contributory infringement. Both Ives and PMA merely state that since the word "Cyclospasmol" appeared on the dispensing label there was per se trademark infringement. In so doing, they read out of §32 the requirement that Ives has the

burden of proving likelihood of confusion.[12] This position is clearly in error. The support which it impliedly finds in the Ives IV opinion profoundly and adversely affects the lawful, comparative use of trademarks.

Ives relies on Boehringer Ingelheim, G.m.b.H. v. Pharmadyne Laboratories, 211 U.S.P.Q. 1163 (D.N.J. 1981), wherein the court stated that it was not certain that the words "generic Persantine," were sufficient to advise consumers that a generic rather than the brand-name drug was being dispensed. The court there believed that "generic Persantine" might not be understood, even though consumers were told orally by the pharmacist that they were getting a generic product at a lower price.

---

[12] See Fisher Stores, Inc. v. All-Nighter Stove Works, Inc., 626 F.2d 193, 194 (1st Cir. 1980); American Footwear Corp. v. General Footwear Co., Ltd., 609 F.2d 655, 664 (2d Cir. 1979), cert. denied, 445 U.S. 951 (1980); Telemed Corp. v. Tel-Med, Inc., 588 F.2d 213, 216 (7th Cir. 1978).

Curiously, the court stated that only the words "generic for Persantine" would be sufficiently descriptive and explanatory to the patient.[13] Id. at 1181.

There is no basis in law for permitting judicial speculation that a consumer might not understand one of the most elementary and basic concepts in the field of prescription medications in lieu of an evidentiary finding of likelihood of confusion. The prescriptions involving "mislabeling" all authorize substitution, which presumes that the physician had advised the patient that a generic would be dispensed.[14] The

---

[13]Thus, the very case cited negates the per se approach in favor of purportedly determining when confusion exists. Moreover, the court's discussion of the issue was entirely speculative since the brand-name company there, as here, introduced no evidence relating to this matter.

[14]See Pharmaceutical Society of State of New York v. Lefkowitz, 586 F.2d 953, 956 (2d Cir. 1978) (Mansfield, J.). See also N.Y.EDUC. LAW §6810(6)(b) (McKinney's Supp. 1981) [Pet.App. 115a].

assumption that patients so informed by their physicians, reminded by the pharmacist that a "generic" was being dispensed, and having paid a lower "generic price"[15] would still not understand what was transpiring is totally unrealistic.

Similarly, the so-called "freedom-of-choice" argument raised by Ives and the amici is totally misplaced. It is the physician's responsibility to advise the patient that a generic will be dispensed. Ives and incongruously, the American Association of Family Physicians, assume, without any basis, that physicians as well as pharmacists will violate their legal and ethical responsibilities, and that a change in capsule color

---

[15]PMA's contenion that there is no such thing as a generic price is in error, as shown by the adoption of generic substitution laws in 49 states which mandate that a lower generic price be charged. New York State also requires that pharmacists must post the brand-name versus generic sale price of the 150 most frequently prescribed drugs. See N.Y.EDUC. LAW §6826 (McKinney's Supp. 1981).

is necessary to compensate for the physician's dereliction.

It was Ives' burden to show by a preponderance of the evidence that a likelihood of confusion existed. No such evidence was introduced, and post hoc speculation cannot correct the manifest error in the Second Circuit's finding of per se trademark infringement in the use of the term "generic Cyclospasmol." Justice Holmes clearly stated the law to be applied, which Ives blithely ignores:

> "When the mark is used in a way that does not deceive the public we see no such sanctity in the word as to prevent its being used to tell the truth. It is not taboo." Prestonettes, Inc. v. Coty, 264 U.S. 359, 368 (1924) [emphasis added].[16]

---

[16] See also Judge Untermeyer's scholarly dissenting opinion in Winthrop Chemical Co. v. Blackman, 246 App.Div. 234, 285 N.Y.S. 443 (1st Dept. 1936). Cf., §33(b)(4) of the Lanham Act [15 U.S.C. §1115(b)(4)].

III. THE BRAND-NAME COMPANIES' ABSOLUTE DENIAL OF FUNCTIONALITY FOR PHARMACEUTICAL COLORS CANNOT BE SUSTAINED

Ives advances the absolute position that despite the findings of the district court there is no functionality for colors in the context of prescription pharmaceuticals. Any concession of functionality would necessarily defeat a finding of liability in this case, since Ives has abandoned the rationale of the Second Circuit that liability can be premised on certain unidentified suggestions in petitioners' respective promotional materials. It would be manifestly unfair to hold petitioners contributorily liable for the acts of unscrupulous pharmacists, if petitioners selected the capsule colors for legitimate competitive reasons. Various aspects of color functionality are proven in this record and by all of the available evidence. This Court should reject Ives' denial and

confirm the role of color as a functional aspect in the commercial and therapeutic success of petitioners' products.

Ives' principal contention is that such functionality can only exist by deceiving the patient. This argument totally misrepresents the record. The trial testimony cited in detail in Inwood's main brief addressed the issue of the effect of a change in capsule color upon patients who are informed that they are obtaining a generic product. There is absolutely no element of deception with respect to this aspect of functionality.

The nature of competition between generic companies and their brand-name counterparts is such that this issue of functionality arises when patients, having previously taken a brand-name product under a prescription which prevented substitution, either on their own initiative

or at the suggestion of their physician, obtain a renewal prescription which for the first time authorizes generic substitution. Patients, knowing that a generic has been dispensed, most frequently discover any difference in color at home, when the product is first used.

Mandatory color differences thus impose the following penalties on patients who in consultation with the physician have opted to at least try a less-expensive generic. Patients will at first believe that a mistake had been made in filling the prescription. Patients must then call or visit the pharmacist and/or the physician to obtain an explanation. More rational patients are thereafter expected to accept the explanation that a change in color should not affect therapeutic efficacy. After all hurdles have been overcome, patients must then evaluate the efficacy of the generic

in comparison to their experience with the brand-name product. Patients are concerned: "Will this product produce the same or different therapeutic effect?" Their eyes tell them every time they look at the medicine that the product is different.

Significant in this respect is the less than ethical campaign of the brand-name companies to plant unfounded fears in the minds of the public about the efficacy of generic drugs. See, e.g., PMA brief at 17-20; Inwood Exh. 6 at 289-307. The myth of brand-name superiority over generics fostered by "fear and smear" tactics has been completely refuted.[17] See FDA Office of Planning and

---

[17]FDA investigations have disclosed that Ives' Isordil has failed to perform its therapeutic functions on various occasions. See FDA Establishment Inspection Reports dated Mar. 31, 1977 and Jan. 25, 1979. Ives' cyclandelate, on another occasion, was found to have had unexplained side effects on a patient and in other instances Cyclospasmol capsules were covered by a mold with a strong odor. See FDA Establishment Inspection Report dated Nov. 2, 1978. Moreover, FDA records

Evaluations, "An Analysis of Prescription Recall Rates" (Apr. 1980) (concluding no difference in quality between generic drugs and their brand-name counterparts). See also Remarks of FDA Commissioner Kennedy reported in "HEW News," P78-34 (Sept. 13, 1978) ("[there is] no difference in the recall records of brand versus generic drugs."). In fact, it is well known that many so-called brand-name products are actually manufactured under contract by

---

(cont.)

show that in 1981 alone, PMA members (including E.R. Squibb, Eli Lilly, Abbott, Hoffman-LaRoche, Upjohn, Pfizer and Mead-Johnson) conducted at least 27 recalls of their "superior" products, due to, for example, non-sterility, sub-potency, lack of homogeneity, mislabeling and the curdling of infant formula. See FDA Enforcement Reports (1981).

generic companies.[18] Yet, the brand-name company attack on generic drugs continues unabated. A patient who decides to try a generic is thus likely to be sensitized to expect a potential difference between brand-name and generic drugs. The further penalty of a difference in color may very well be the straw that breaks the camel's back.[19]

Ives' insistence that a difference in

---

[18] See, e.g., Inwood's Exh.6 at 155-56 (noting Mylan manufactures Erythromycin for three PMA members for distribution under their brand name. Mylan sells the same product to petitioner Sherry. The branded versions of the identical product sells at retail for 2 or 3 times more than the generic product.) See also "Drug Product Selection," Staff Report to the Federal Trade Commission (Bureau of Consumer Protection, Jan. 1979) at 51-54.

[19] Ives suggests that physicians should advise their patients that the medicine they get under a generic prescription may be in a different color. Since patients know they will be receiving a generic, there is no reason for it to be in a different color. Moreover, communicating a color difference will not resolve, and may even emphasize, the patient's potential adverse reaction to this difference. Requiring physicians to make such explanation is another burden which the brand-name companies can promote as a reason for not prescribing generically. See also n.26, infra.

color will not matter to the patient is an attempt to deny a commonly recognized and indisputable scientific fact. At a major symposium sponsored by the American Medical Association to discuss the issue of bio-equivalence of comparable drugs, it was noted:

> "DR. SCHIFFMAN [Director of Medical Terminology, American Medical Association]: [p]atient acceptance, not only of medications but of the doctor himself, ... are a real part of medicine and are extremely important.
>
> "For example, Dr. Barclay who is an Assistant Executive Vice President of the AMA and who has been a practicing physician for a number of years, feels very strongly about this. He believes that a patient definitely can be influenced by the appearance of a medication. You know the old story about the 'little old lady' who receives a different color tablet than the last one she got. Her response is, 'The pink pill is not doing me any good Doc, whereas the green one was great.' I am told that this is not a straw man; it is a real effect. This is an intangible that must be taken into account in any type of equivalency program you devise.

* * *

"DR. WAGNER [Professor of Pharmacy, American Society for Clinical Pharmacology & Therapeutics]: [U]pjohn sells PAC's: one green, one white. Now, if you put a patient on the green, you will never convince them that the white is the same. It has happened so many thousands of times, that people just gave up trying to convince the patient otherwise. So, they produce them both. You cannot switch a patient once they're on one, because they just will never believe that it is the same pain killer.

"Every pharmacist in this room, who has ever practiced, has seen the look on the 'little old lady's' face if she gets the 'wrong-colored pills,' or tablets. If you haven't been in a pharmacy and seen this, then you shouldn't even be commenting on the subject . . . Patients are horrified, and it is a big shock to them .... Now, it may be unimportant to you as a scientist, but it is very important to the 'little old lady.'" See "The Scientific Evaluation of Drug Equivalency", Proceedings of a Colloquium - Washington, D.C. - June 14, 1974 (A. Brest, Editor, EXCERPTA MEDICA, Wash. D.C., 1974) at 58-59, 65 [emphasis added].[20]

---

[20]As one commentator recently noted in discussing this Court's review of Ives IV:

"In the middle [of this controversy] are, perhaps, millions of financially strapped

Ives' own witness confirmed the patients' association of color with their comparative efficacy evaluation of medicines:

> "It is very simple. There are sometimes when you're talking to a patient and they say to you, gee, you know, the last batch of red tablets you gave me weren't quite as good as the green batch." [Tr. 364, J.A.188a]

In more candid moments, the brand-name companies themselves recognize the very functionality which they so strenously deny in this case. A leading manufacturer of pharmaceutical capsules (and a member of PMA) is Parke-Davis, which has extensively promoted the functionality of capsule colors in its publication "Capsule Color

---

(cont.)

> elderly patients with, in many cases, fading eyesight, who identify their heart pills by their color to distinguish them from their liver pills and their stomach pills." Dickinson, "Washington Report" PHARMACEUTICAL TECHNOLOGY, Oct. 1981 at 23.

Considerations" (Parke-Davis, Division of Warner-Lambert Co. 1980) ("Parke-Davis"):[22]

> "Parke-Davis Can Provide You with the 'Color-Edge'
>
> "Our color laboratory, our equipment and our color experts are at your command to come up with the right colors for you. Contact our technical sales representative. Show him the color combination you have in mind . . . . If you need guidance in psychologically appropriate colors, we can provide several papers on the subject. Better still, let our color consultants come up with a few suggestions." Id. at 3.

Patient compliance (also referred to by Parke-Davis)[23] is an additional critical

---

[22]This publication is on file in Warner-Lambert's corporate services library. See letter from Jacob Laufer to Edith Chapman, January 27, 1982.

[23]The Parke-Davis material which has been filed with the Court also notes:

> "Numerous investigations in the U.S., England and Continental Europe have established that patients show preferences -- and aversions -- to various colors.
>
> • • •
>
> "Two-color capsules indicate a change from one condition to another. Again, using red and dark blue as examples, red conveys irritation and inflammation and dark blue represents sedating these conditions. Because the therapeutic effect is conveyed by the use of two colors -- and because two colors provide

factor in an understanding of functionality of color. The trial testimony demonstrated that patient compliance with doctor's instructions is frequently poor. [Tr. 829, J.A. 279a] See also Blackwell, "Treatment Adherence" 129 BRIT.J.PSYCH. 513, 517 (1976). Consequently, a change in color which causes a negative reaction in patients must have an adverse reaction on the already poor rates of patient compliance.

(cont.)

more accurate identification, most pharmaceutical manufacturers favor two colors.

"While the functional choice of two colors to express the action of the preparation is of paramount importance, asethetically pleasing color combinations also should be selected whenever possible. Patients also respond positively to such combinations.

"A capsule which, through it color(s) conveys psychologically that it will be beneficial, builds patient confidence in the preparation. This leads to better patient compliance." Id. at 2. Accord, Buckalew & Coffield, "An Investigation of Drug Expectancy as a Function of Perceptual Characteristics" (Manuscript submitted for publicaton, Alabama A&M, 1982).

No substantive response to the undeniable scientific evidence is made by Ives.[23] PMA argues that the colors here do not serve a psychological purpose because Ives claims they were arbitrarily selected. Ives similarly argues that these specific colors have not been shown to have a placebo efffect.

Both arguments are clearly wrong. Capsule color has its effect on therapy, irrespective of whether the manufacturer selects the colors for that purpose. Ives' reliance on testimony that similarity of

---

[23]See also Jacobs & Nordan, "Classification of Placebo Drugs: Effect of Color," 49 PERCEPTUAL & MOTOR SKILLS, 367-372 (1979); Blumenthal, Burke & Shapiro, "The Validity of Identical Matching Placebos," 31 ARCH.GEN.PSYCH., 214 (Aug. 1974); Biron & Caringnan, "Chromo Confusion: A New Type of Pill - Pill 'Interaction' in Cardiology," 110 CMA JOURNAL, 1346-48 (June 22, 1974); Schwartz, "The Elderly Patient and His Medications," GERIATRICS, 517 (June 1976); 47 F.R. 444, 447 col.2 (Jan. 5, 1982) (FDA panel notes that major drawback in use of activated charcoal as anti-toxin is its black color, which often causes children to refuse it); 46 F.R. 47,623 col.3 (Sept. 29, 1981) (discussing color coding labeling requirements for blood and blood components).

color is not medically necessary thus misses the point. The issue is not whether similarity of color is absolutely necessary but, rather, whether it is desirable and beneficial. Patients who receive generic drugs should be entitled to have the same psychological color support as patients who receive a brand-name medication.

PMA has also urged this Court to consider the series of New Jersey cases dealing with this issue, but it intentionally omits the direct evidence in those cases that the brand-name companies have adopted the very criteria discussed above by Parke-Davis and in the scientific literature. PMA members utilize these criteria in both the selection

and promotion of their drug colors.[24]

The arguments against color similarity ignore the basic problem; that color monopoly is at the heart of the promotional

---

[24]A document authored by PMA member Merck was filed in opposition to Merck's motion for summary judgment in the case of Biocraft Laboratories, Inc. v. Merck & Co., Inc., ____ F.Supp. ____, Civ. Action No. 77-693 (D.N.J. Oct. 2, 1980), and discloses the following:

> "The psychological importance of color to a patient has been documented." Doc.Prod. #M39257 [emphasis added].
>
> * * *
>
> "Color is thought to be psychologically important to the patient . . . Brown and grey are not well-accepted colors because of their association with dirt and death. Well-accepted colors include light blue, peach and a light red." Doc.Prod. #M39259 [emphasis added].
>
> * * *
>
> "Physicians have also documented studies associating potency with color (i.e., red)." Doc.Prod. #M39267.
>
> * * *
>
> "Proper choice of color is particularly essential in physchotherapeutic agents. Marketing should refer to past studies on selection of color." Doc.Prod. #M39271 [emphasis added]. See Exh.24 in Opposition to Merck & Co.'s motion for summary judgment; Merck internal memorandum and attachments from J.E. Allegretti to RIMM members, dated Aug. 29, 1978.

efforts of brand-name companies to convince their accounts, including physicians, not to buy generic substitutes. One PMA member, for example, succeeded in persuading pharmacists and a medical center not to purchase competitive products on account of its products' claimed color advantage.25

Doctors have publicly and frequently testified concerning their opposition to potential switches in the color of

---

25See Exh.4, 9 and 10 filed in opposition to Merck's motion for summary judgment; Merck Product Related Information Memo, No. 13 at 1-3 (Mar. 4, 1976), Doc.Prod.#M21933-M21935; Region Managers' Activities Report, Monthly Summary, at 7 (May 1976), Doc.Prod.#M20832; Region Managers' Activities Report, Monthly Summary, at 4 (Feb. 1976), Doc. Prod.#M20817. Despite such evidence, summary judgment sanctioning a monopoly of color was granted. See Biocraft Laboratories v. Merck, supra. It is clear that some district courts have construed SK&F Co. v. Premo Pharmaceutical Laboratories Inc., 625 F.2d 1055 (3d Cir. 1980), as a mandate to disregard any evidence of color functionality. For another extreme example of this unfortunate consequence, see Artus Corp. v. Nordic Co., 512 F.Supp. 1184, 1189 (W.D.Pa. 1981) (plaintiff permitted to acquire monopoly for 14 colors where entire industry used 14 colors to identify thickness of construction materials).

prescription drugs. For example, Dr. John Budd, then President-Elect of the American Medical Association testified before Congress that:

> "Such factors as differences in the dosage form or in taste, color, size, or shape of a tablet can be critical in determining whether the patient will 'take' the prescribed medicine." "Prescription Drug Labelling & Price Advertising," Hearings Before the Subcomm. on Consumer Protection and Finance for the House Comm. on Interstate & Foreign Commerce No. 94-153, at 286 (94th Cong., 2d Sess., Aug. 30, 1976).[26]

---

[26]Dr. Budd also stated:

> "However, I encountered frequently the annoying situation that a patient would have the prescription filled elsewhere and get a tablet or capsule or a medication that appeared different from the one he had been used to getting, and then he would phone me and ask why I had changed the drug, or had the pharmacy made a mistake? I would have to phone the pharmacist and find out what was actually prescribed, and then phone the patient and tell him, yes he had a different brand, but essentially the same drug.
>
> "For many physicians, this is extremely irritating when they write generic prescriptions, this constant phoning back and forth on the part of the patient, because each time he has the prescription filled he might

One of the more ironic examples of inconsistencies in the denial of color functionality is found in the brief of amicus Medicine in the Public Interest ("MIPI"). MIPI claims that color plays the least important role in medical treatment. MIPI's counsel must have been unaware that Dr. Louis Lasagna (who is identified as a member of MIPI's Board of Directors in the booklet it filed with the Court) has published in a scientific journal his view that drug identification by color for the patient is of great importance to avoid confusion and for effective communication by physicians to patients. To apply Dr. Lasagna's approach would require prescribing by brand name only. See Mazzullu & Lasagna, "Take

---

(cont.)

get a different appearing tablet. Patients are anxious enough about their illness, and it is unfair to load on them the further anxiety that perhaps a mistake was made in filling the prescription." Id. at 291 [emphasis added]

Thou . . . But is Your Patient Really Taking What You Prescribed?", DRUG THERAPY at 11-15 (Nov. 1972).[27]

In addition, the record presents abundant evidence that uniformity of color would have other significant functional advantages in the public interest. Comingling of medications in a single container for the purpose of facilitating convenient administration during the course of a given day (especially while a patient is away from home) is an accepted fact of medical life. The inevitable practice of comingling is made less dangerous and safer when colors are uniform. In the absence of color uniformity, patients would have to re-learn a new series of color schemes with each

---

[27]Dr. Lasagna also noted a patient who suffered severe congestive heart failure as a result of confusion in color and stresses the importance of color in effective communication between doctor and patient. Id. See also Lasagna, "Placebos," 193 SCIENTIFIC AMERICAN 68-71 (1955).

dispensed medication. Worse, patients risk making an error based upon their failure to remember the latest series of colors for their respective medicines.[28]

If the brand-name companies obtain a monopoly on color, the public interest will be adversely affected by the hazards and inconvenience involved in identifying medicines as specific therapeutic agents. The testimony here shows that patients do identify their medicines in terms of color for a specific medical condition. Ultimately, color monopoly would mean that the consumer would be deprived of color as an identifying factor. We urge this Court to recognize and

---

[28]See FDA CONSUMER, Oct. 1980 at 30, showing that the impact of uniform color identification, even upon professionals is a matter of critical concern. One FMA member marketed a drug known to precipitate attacks of acute glaucoma, erroneously labeled as a vitamin. Public injury was avoided only because a pharmacist noticed that the purported vitamin tablet was not in the standard orange color.

affirm that color in the field of medicine[29] is just as functional, if not more so, than the everyday color functionality which is recognized in so many other areas of commerce.[30]

---

[29]Prior to the recent spate of litigation, the importance of color in drugs was never questioned:

> "The use of color in foods, drugs and cosmetics, though largely of value from the point of view of enhancing the marketability of the articles involved, is in many cases, also in the consumer interest and affirmatively desired by consumers. . . . In drugs, color additives are much used for ready identification, thus helping the pharmacist, the physician, the nurse, and the patient to avoid dangerous mistakes in choosing the wrong bottle or box." Senate Report. #795, Color Additive Amendments of 1959, Report to Accompany S.2197 (86th Cong., 1st Sess. 1959) at 11 [emphasis added].

[30]See, e.g., Plastilite Corp. v. Airlite Plastics Co., 390 F.Supp. 1141, 1148 (D.Neb.), rev'd on other grounds, 526 F.2d 1078 (8th Cir. 1975), cert. denied, 425 U.S. 938 (1976); Vitarroz Corp. v. River Brand Rice Mills, Inc., 266 F.Supp. 981, 984-985 (S.D.N.Y. 1967); Schmidt Mfg. Co. v. Sherrill Industries, Inc., 249 F.Supp. 480, 484-488 (W.D.N.C. 1965). See also 46 F.R. 32,880 (June 25, 1981) (Department of Transportation study recommending national standards of color and shape for traffic signs.).

This is not the first time that the supposed consequence of "illegal substitution" has been raised as an argument against a competitive product being marketed in a familiar and accepted color. One dramatic example involved the producers of butter, who asked Congress to require that margarine, sometimes passed off as butter, be sold only in a color other than the familiar yellow. The following description by Senator Fulbright in his ultimately successful opposition to the then-requested color monopoly virtually tracks the outline of the instant controversy:

(cont.)

See generally Hackl, "Color: A Language of Persuasion," ART PRODUCT NEWS, Vol.3, No.6 (1981); Hackl, "Hidden Meanings of Color," GRAPHIC ARTS BUYER, Vol.12, No.5 (1981); B.W. Most, "Color Scheming," AMERICAN WAY, 28 (May 1981); Dr. Max Luscher, "THE LUSHER COLOR TEST" (Pocket Books, NY 1971) (Trans. fr. German by Ian Scott). Other examples of the function of color can be found in Public Citizen v. Foreman, 631 F.2d 969, 973 (D.C.Cir. 1980) and Certified Color Mfrs. Ass'n v.

"The butter industry knows very well that consumers want their table spread whether margarine or butter, served yellow. Imagine, for example, eating green margarine or green butter, even if it were just as nutritious and tasty as yellow margarine or yellow butter. Imagine drinking red milk, even though the coloring which made it so was perfectly harmless. We are all familiar with the common practice with respect to oranges. I do not think the coloring of an orange improves it any, but, for the same kind of reason, everyone colors oranges today in the markets. It is merely a habit.

"We develop a set of food habits, which include eye appeal, as well as taste appeal, just as we develop other habits. We have been taught to like our butter served yellow and our margarine served yellow. 96 CONG.REC. S53-54 (daily ed. Jan. 4, 1950) [emphasis added].

If Ives and other brand-name companies are given the right to monopolize their color configurations, it is they who will be competing unfairly with generic drug companies. Generic products will be affected by adverse patient reactions, thus reinforcing

---

(cont.)

Matthews, 543 F.2d 284, 289 and n.15 (D.C.Cir. 1976).

the brand-name companies' arguments that only the more-expensive brand-name product should be prescribed and dispensed. Surely the brand-name companies have no right to exact such a price from the American people.[31] Although, as the Parke-Davis materials point out, "trying to explain colors in words is like trying to describe music instead of playing it," Parke-Davis at 3, the record is clear that the arguments advanced by the brand-name companies are but a pretext for achieving a valuable monopoly of capsule color, which will subject the public and the generic drug industry to a significant health and economic disadvantage.

---

[31] Cf. Pharmaceutical Manufacturers Ass'n v. Whelan, ___ N.Y.2d ___, No. 650 (Dec. 22, 1981).

IV. IVES' STANDARD FOR CONTRIBUTORY LIABILITY SHOULD BE REJECTED AS CONTRARY TO THE PUBLIC INTEREST

Ives' suggestion that contributory liability should be found solely because petitioners could have "reasonably anticipated" that some unlawful use might be made of their products is illogical. Mere awareness that illegal substitution exists should not be sufficient to impose contributory liability. See Coca-Cola Co. v. Snow Crest Beverages, 64 F.Supp. 980, 989 (D.Mass. 1946), aff'd, 162 F.2d 280 (1st Cir.), cert. denied, 332 U.S. 809 (1947).

The facts of this case amply show why the rule suggested by Ives should not be adopted. The alleged unlawful acts to be anticipated by petitioners in this case are claimed to have been of two types. The one primarily relied upon by Ives below relates to the "additional evidence" of mislabeling in the New York survey. Even assuming that

such "mislabeling" could be anticipated,[32] capsule color has not been shown to have any causal relationship to the acts of mislabeling by pharmacists. The so-called mislabeling occurs in instances where substitution is lawful, and the pharmacist is free to substitute a generic product, even if it were in a different color. "Mislabeling" does not derive from any ulterior motive, and capsules of a different color could be "mislabeled" just as easily as those of a similar color. How a change in color would cause a pharmacist to label differently remains a complete mystery.

The second prong of Ives' "reasonably anticipate" standard addresses the

---

[32]We find totally illogical Ives' argument that petitioners in 1975 and 1976, when these products were first sold, could have anticipated that pharmacists would "mislabel" lawfully substituted generics within the meaning of a statute which had not yet been enacted, and did not take effect until April 1, 1978.

unfortunate, but inevitable, fact that petitioners and everyone else can "anticipate" that some illegal substitution occurs in the marketplace. Illegal substitution, as shown on this record, is de minimis. In a nationwide shopping of known "bad actors" at the outset of the litigation, Ives was able to unearth no more than one pharmacy in Tylertown, Mississippi, one pharmacy in Pennsylvania, and two pharmacies in New York, which illegally substituted a generic product for Cyclospasmol.[33] The Court of Appeals in Ives II found that this amount was de minimis and not probative for any purpose in this litigation. Ives II at Pet.App. 36a; 52a-53a. However, Ives elected not to conduct any further surveys for the

---

[33]Ives now concedes that the Michigan shoppings failed to show illegal substitution. Rather, it argues that notice of lawful substitution may have been inadequate. Ives' description is a post hoc effort to salvage this evidence.

purpose of measuring illegal substitution.[34] A survey conducted by petitioner Premo, showed that in New York, out of 25 pharmacies shopped, there was not one single instance of illegal substitution. [Pl.Ex. 142, J.A. 375a-382a]. On this record, Ives' professed concern about illegal substitution is transparently frivolous.

Inwood requests that in view of the importance of the issue and the need for a definitive ruling this Court should not limit itself to a holding based solely upon the fact that this record shows virtually

---

[34]Ives repeats the statement made by the majority below that it is surprising that it could produce as many instances as it did, given pharmacists' reluctance to admit acts of illegal substitution. Ives, however, did not obtain its de minimis evidence of illegal substitutionn by polling pharmacists for admissions of illegality. The evidence, such as it was, was obtained by presenting unsuspecting pharmacists with test prescriptions, which after dispensing, would show whether that pharmacist illegally substituted. No "admissions" were involved and Ives' decision not to conduct another survey shows that it was convinced that a second survey would be fruitless.

no illegal substitution of any consequence. As a legal principle, the fact that some illegal substitution may occur and the mere fact that a generic drug company can anticipate that it will occur to some unspecified extent, and by some unknown pharmacists, should not by itself be a predicate for contributory liability.[35]

First, the brand-name companies make virtually no effort to monitor the acts of pharmacists and to enforce the requirements of state laws against illegal substitution. Instead, they seek to place the entire burden of protecting their good will against

---

[35]See e.g., Famolare, Inc. v. Melville Corp., 472 F.Supp. 738, 746 (D.Hawaii 1979), aff'd, 652 F.2d 62 (9th Cir. 1981); McCarthy, TRADEMARKS AND UNFAIR COMPETITION §25.2 at 175 (1973); cf., 3 NIMMER ON COPYRIGHT, §12.04 at 12-39 (1980) ("Certainly it would be absurd to hold the manufacturer and seller of a printing press liable as contributory infringers because the buyer uses such press for infringing purposes.")

illegal substitution upon the generic drug manufacturers.[36]

Second, there is no evidence that a change in capsule color will eliminate illegal substitution. In one recent case, there was striking evidence that a pharmacist had illegally substituted, even though the color of the drugs in question were dissimilar from the color of the respective brand-name drugs. See A.H. Robins Co. v. Medicine Chest Corp., 206 U.S.P.Q. 1015 (E.D.Mo. 1980), Transcript of Proceedings at 252-255.[37]

---

[36]The problem of illegal substitution would be eliminated if brand-name companies individually wrapped or blister packed each capsule. This traditional type of "trade dress" distinguishes each capsule from its counterpart. Ives in fact markets its cyclandelate product in such a form. See Pl.Exh.13N (advertising advantages of strip packages).

[37]It is unreasonable to burden competition by granting the brand-name companies a color monopoly solely because illegal substitution, the extent of which is unknown, may be reduced, if at all, by an

Finally, the doctrine of contributory infringement should have, and has always had, an element of wrongful intent or action as its foundation for a finding of liability. See cases cited in Ives I at Pet.App. 13a. In the absence of any direct inducement, an act of suggestion, or intent to profit from the supposedly anticipated illegal conduct, the standard for contributory liability should rest on much more than just the likelihood that a portion of the marketplace will abuse a given product. Where the primary method of sale of prescription drugs is non-infringing, the fact that an indeterminable minority may violate the law should not subject a good-faith marketer to contributory liability. Compare 17 U.S.C. §271(b).

This Court should adopt the standard of contributory liability enunciated by

---

(cont.)

amount which is also unknown.

Judge Friendly in Ives II. Contributory liability should not be found unless the contributor acts wrongfully by suggesting by way of promotion that the wrongful act be committed or by participating in the wrongful act by continuing to sell to a particular pharmacist whom it knows or has reason to know is engaged in unlawful activity. These two criteria for liability embody a basic fairness to the manufacturer so that it is not held liable for the intervening decision of a third party to commit a criminal offense. As noted by Justice Holmes:

> "In some cases where an ordinary article of commerce is sold nice questions may arise as to the point at which the seller becomes an accomplice in a subsequent illegal use by the buyer. It has been held that mere indifferent supposition or knowledge on the part of the seller that the buyer of spirits or liquor is contemplating such unlawful use is not enough to connect him with the possible unlawful consequences, Graves v. Johnson, 179 Mass. 55, but that if the sale was made with a view to the illegal resale the price

could not be recovered." Kalem Co. v. Harper Bros., 222 U.S. 55, 62 (1911).

The "nice questions" anticipated by Justice Holmes over seventy years ago are thus squarely presented for decision here. The unqualified mere "anticipation" rule suggested by Ives should be rejected because it threatens to permit the perpetuation of color monopolies contrary to the public interest in fully effective competition and fully effective medicine.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the ruling of the Second Circuit be reversed and that the judgment of the District Court be reinstated.

Respectfully submitted,

MILTON A. BASS
JACOB LAUFER
STEVEN R. TROST
LAWRENCE H. ROTH

BASS, ULLMAN & LUSTIGMAN
Attorneys for Petitioner
Inwood Laboratories, Inc.